

08-16-04

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PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Application Number	10767,824
Filing Date	January 29, 2004
First Named Inventor	Cooperstone
Art Unit	1614
Examiner Name	
Attorney Docket Number	AM-101305USA

Total Number of Pages in This Submission

6 + docs

**ENCLOSURES (Check all that apply)**

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment/Reply
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/  
Incomplete Application
- ☐ Response to Missing Parts  
under 37 CFR 1.52 or 1.53

- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a  
Provisional Application
- ☐ Power of Attorney, Revocation  
Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) \_\_\_\_\_

- ☐ After Allowance communication  
to Technology Center (TC)
- ☐ Appeal Communication to Board  
of Appeals and Interferences
- ☐ Appeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please  
Identify below):

**Remarks**

Customer No. 38199; Express Mail No. EU531571559US

**PCT Search Report and documents:**

Document HH - Antifibrosis effect of interferongamma . . .  
Document II - Rapamycin Reduces Expression of Fibrosis-Associated Genes . . .  
Document JJ - Effects of interferon-gamma, and rapamycin . . .  
Document KK - Pharmacokinetics (poster session - 12 poster titles)

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm or Individual name	Cathy A. Kodroff
Signature	HOWSON AND HOWSON <i>Cathy A. Kodroff</i>
Date	August 13, 2004

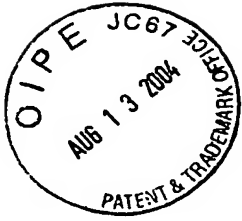
**CERTIFICATE OF TRANSMISSION/MAILING**

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

Typed or printed name			
Signature		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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AM-101305USA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/767,824 Confirmation No.: 5606  
Applicant : Cooperstone, et al.  
Filed : January 29, 2004  
TC/A.U. : 1614  
Examiner :  
Customer No. : 38199  
Title : METHOD OF TREATING HEPATIC FIBROSIS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicants submit to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A/B is attached and a copy of the documents are enclosed herewith. This Information Disclosure Statement is filed within one month of the mailing of an International Search Report in the counterpart international application in order to disclose documents first cited therein. Additionally, this Information Disclosure Statement is being filed before the receipt of a first Office Action. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

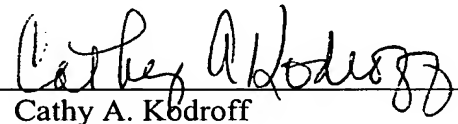
## REMARKS

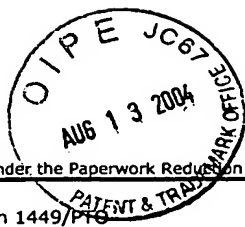
Listed below are documents cited in the International Search Report mailed July 19, 2004 in counterpart International Patent Application No. PCT/US2004/002365, filed January 29, 2004. A copy of the Report is enclosed, together with copies of the four documents not previously disclosed. Document 1 [Zhu, et al., Rapamycin inhibits hepatic stellate cell proliferation in vitro and limits fibrogenesis in an in vivo model of liver fibrosis, Gastroenterology, vol. 117, no. 5, pp. 1198-1204 (November 1999)] of the International Search Report was previously disclosed in this application as document "GG" in the Supplemental Information Disclosure Statement filed May 11, 2004.

The Examiner is respectfully requested to consider the enclosed documents identified in this paper and in the attached Form PTO/SB/08A/B during the course of examination of this application.

Respectfully submitted,

HOWSON AND HOWSON  
Attorneys for Applicants

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/767,824
				Filing Date	January 29, 2004
				First Named Inventor	Cooperstone
				Group Art Unit	1614
Sheet	1	of	1	Examiner Name	
				Attorney Docket Number	AM-101305USA

#### NONPATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	HH	<b>SHIBATA NORIKUNI</b> , <u>Antifibrosis effect of interferongamma (IFNgamma) and rapamycin (Rapa) in immortal human hepatic stellate cells</u> , Database Biosis Online!, 2002, pp. 185-197, Database accession no. PREV200300151275, ISSN: 0386-5924, vol. 28, pp. 185-197, Biosciences Information Service, Kawasaki Igakkai Shi [Abstract]	
	II	<b>S. JAIN, ET AL.</b> , <u>Rapamycin Reduces Expression of Fibrosis-Associated Genes in an Experimental Model of Renal Ischaemia Reperfusion Injury</u> , Transplantation Proceedings, February 2001, pp. 556-558, vol. 22, no. 1-2, ISSN: 0041-1345, Elsevier Science, Inc., New York, NY	
	JJ	<b>YOSHIHIDE ARISAKA</b> , <u>Effects of interferon-gamma and rapamycin on transforming growth factor-beta-induced liver fibrosis in an organotypic slice culture</u> , Database Chemabs Online!, 2003, pp. 597-603, Database accession no. 2004:146496, ISSN: 0029-0424, vol. 62(11), Nihon Daigaku Igakkai [Abstract]	
	KK	<b>L. LOPEZ-LAZARRO, ET AL., F. LOKIEC, ET AL., H.C. SWAISLAND, ET AL., U. MAYER, ET AL., L. PLASSWILM, ET AL., G. CARTEI, ET AL., F. LOKIEC, ET AL., M. AIROLDI, ET AL., J. BONI, ET AL., O. TOMOYUKI, ET AL., O. JUAN, ET AL., T. OE, ET AL.</b> , <u>Pharmacokinetics poster session (12 individual poster titles)</u> , European Journal of Cancer, October 2001, pp. S66-S69, vol. 37, Pergamon Press, Oxford, GB [Posters]	

Examiner Signature		Date Considered	
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\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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